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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,228	07/31/2003	Jaya Pathak	50623.251	1730

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EXAMINER	
LIN, JAMES	
ART UNIT	**PAPER NUMBER**
1762	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/631,228	PATHAK ET AL.	
	Examiner	Art Unit	
	Jimmy Lin	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *7,11,12,14 and 19-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-10,13 and 15-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-10, 13, and 15-18 in the reply filed on 8/10/06 is acknowledged.

2. Claim 7 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/10/06.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-6 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan et al. (U.S. Publication 2004/0063663), Inoue et al. (U.S. Patent 5,762,944), and Hughes et al. (U.S. Patent 5,756,659).

Claims 1,13: Buchanan discloses a method of making a carrier polymer that is used to coat the surface of a stent to provide controlled and sustained release of an anticoagulant drug at the preferred site [0065]. The coating can be formed by putting the carrier polymer along with

the other additives into a twin screw extruder [0051]. The polymer can be a thermoplastic material [0059].

Buchanan does not teach introducing a fluid into the extruder and removing at least a volume of the fluid from the extruder such that an impurity is at least partially removed with the fluid.

Inoue teaches a method of a coating for a stent, wherein the coating comprises a polymer (col. 3, lines 1-31). Inoue recognizes the need to wash the polymer to remove impurities in the method of making medical devices such as a stent. The impurities can include a solvent, an unreacted portion and an impurity (col. 6, lines 38-43). Hughes teaches a method of removing impurities, such as unreacted monomer, solvent, and thermally unstable species, from a molten polymer inside a twin-screw extruder. A stripping agent is introduced into the polymer melt stream and the polymer/stripping agent mixture is homogenized in a mixing zone. At least some of the stripping agent and impurities are removed from the polymer (col. 3, lines 10-33; Fig. 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have introduced a fluid into the extruder to have removed impurities from the polymer of Buchanan because one skilled in the art would have recognized the need to remove impurities in a method of making a material for a medical device and because Hughes teaches that such an in-situ process is suitable in the art of removing impurities from a polymer. The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945).

Claim 2: Buchanan teaches that the extruder is kept at a temperature between 100-200 °C [0051]. Such temperatures are greater than the boiling temperature of the solvents of Inoue at ambient pressure. Therefore, the solvents of Inoue would have been exposed to a temperature greater than the boiling temperature at ambient pressure.

Claim 3: Buchanan teaches that a single screw extruder can also be used [0051].

Claim 4-5: Buchanan teaches that the polymer must be melted in the extruder [0051].

Claim 6: Inoue does not explicitly teach that the fluid is a type to physically entrap the impurity without dissolving the impurity. However, the Applicant teaches that water is a suitable "non-solvent" for physically entrapping an impurity (pg. 8, lines 18-21). Inoue teaches that

water is a suitable fluid (col. 6, lines 38-43). Therefore, using water as the particular fluid would have necessarily entrapped and removed some type of impurity.

Claim 8: Hughes teaches that a second stripping agent can be introduced to the extruder, wherein the stripping agent removes an impurity from the polymer (col. 3, lines 33-45).

Claim 9: Buchanan teaches that a suitable thermoplastic can be polyethylene-vinyl acetate copolymer (i.e., an ethylene-vinyl acetate copolymer) [0059].

Claim 10: Inoue teaches that a suitable solvent can be acetone (col. 6, lines 38-43).

6. Claims 13 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan '663, Inoue '944, and Hughes '659, as applied to claim 1, and further in view of Berg et al. (EP 0623354).

Buchanan, Inoue, and Hughes are discussed above, but do not explicitly teach that the polymer can be combined with a solvent. However, Berg teaches that a solution comprising a polymer and solvent can be applied to the coating of a stent and then evaporating the solvent (abstract). The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have applied the polymer of Buchanan, Inoue, and Hughes in a solvent solution and then evaporating the solvent because Berg teaches that such a coating method is suitable in the art of coating a stent.

Claims 15-18 are rejected for substantially the same reasons as claims 2, 4-5, and 9-10 above.

Response to Arguments

7. Applicant's arguments filed 1/8/2007 have been fully considered but they are not persuasive.

Claims 1-6 and 8-10 as rejected over Buchanan '663, Inoue '944, and Hughes '659:

The Applicant argues on pg. 7 that the need for purifying the polymer of Inoue would not apply to a completely different polymer or polymers as disclosed in Buchanan. However, the basis of the rejection is that Inoue teaches the need to remove impurities, such as solvents, from a

polymer used to make an implantable medical device. The type of polymer that Inoue uses is irrelevant because other types of polymers used to make an implantable medical device can also have impurities.

The Applicant argues on pg. 7 that Buchanan does not indicate that impurities or unreacted species are a problem or even mention them. However, Inoue does teach that residual solvent is a problem and Buchanan at least teaches that a solvent used in the acylated CD is an impurity ([0014] of Buchanan). Because the acylated CD (i.e., the inclusion complex) is mixed with the polymer [0051], residual solvent would mix with the polymer.

The Applicant argues on pg. 7 that Inoue does not disclose cleaning a polymer for a medical film that is not implantable. However, Inoue explicitly teaches that applicable medical apparatuses may include expandable metallic stents inserted **in the blood vessel** for expanding the blood vessel (col. 3, lines 3-6). Without even considering the actual meaning of a "stent", inserting the stent in the blood vessel clearly suggests that the device is implantable. In addition, **the Applicant explicitly teaches that a stent is implantable** (pg. 2, lines 1-2 of present specification). Inoue teaches that the antithrombic coating can be applied to the stent. The antithrombic coating can then be interpreted as the stent because the coating is part of the stent.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Iguchi et al. (U.S. Patent 5,756,553) recognizes the need to remove impurities from polymers used for medical devices (col. 4, line 66 – col. 5, line 2).

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

polymer used to form coating on an implantable medical device. The type of polymer that Inoue uses is irrelevant because other types of polymers used to make an implantable medical device can also have impurities.

The Applicant argues on pg. 7 that Buchanan does not indicate that impurities or unreacted species are a problem or even mention them. However, Inoue does teach that residual solvent is a problem and Buchanan at least teaches that a solvent used in the acylated CD is an impurity ([0014] of Buchanan). Because the acylated CD (i.e., the inclusion complex) is mixed with the polymer [0051], residual solvent would necessarily mix with the polymer.

The Applicant argues on pg. 8 that Inoue discloses cleaning a polymer for a medical film that is not implantable. However, the Applicant is directed to col. 3, lines 1-6 of Inoue, wherein Inoue discloses:

> The antithrombic coating of the invention is manufactured by coating the surface of medical [apparatuses] with the antithrombic resin of the invention. Applicable medical apparatuses may include, for example, expandable metallic stents inserted in the blood vessel for expanding the blood vessel.

As noted by the Applicant, the antithrombic coating of Inoue is uniformly applied to a columnar core rod (col. 6, lines 32-33; see also lines 48-50). It is evident that the columnar core rod can be a stent because Inoue clearly suggests that the antithrombic coating of the invention can be applied to stents. There is no suggestion that the antithrombic coating is "used as a medical film such as cataplasm poulticed to cure burns or the like", as suggested by the Applicant. The Applicant does not explain how the coating of the core rod translates into the above-mentioned medical film used for non-implantation purposes. Therefore, Inoue teaches that the antithrombic/polymer coating can be applied onto a implantable medical device.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Iguchi et al. (U.S. Patent 5,756,553) recognizes the need to remove impurities from polymers used for medical devices (col. 4, line 66 – col. 5, line 2).

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jimmy Lin whose telephone number is 571-272-8902. The examiner can normally be reached on Monday thru Friday 8AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tim Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JL

JL

KEITH HENDRICKS
PRIMARY EXAMINER